BONINE- meclizine hydrochloride tablet, chewable WellSpring Pharmaceutical Corporation

Disclaimer: Most OTC drugs are not reviewed and approved by FDA, however they may be marketed if they comply with applicable regulations and policies. FDA has not evaluated whether this product complies.

BONINE®

MECLIZINE HYDROCHLORIDE • ANTIEMETIC

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BONINE®

MECLIZINE HYDROCHLORIDE • ANTIEMETIC

Drug Facts

Active ingredient (in each tablet)

Meclizine HCl 25 mg

Purpose

Antiemetic

Uses

prevents and treats nausea, vomiting or dizziness associated with motion sickness

Warnings

Do not use in children under 12 years of age unless directed by a doctor.

Do not take this product, unless directed by a doctor, if you have

- glaucoma
- trouble urinating due to an enlarged prostate gland
- a breathing problem such as emphysema or chronic bronchitis

Do not take this product if you are taking sedatives or tranquilizers, without first consulting your doctor.

When using this product

- do not exceed recommended dosage
- you may get drowsy
- alcohol, sedatives, and tranquilizers may increase drowsiness
- avoid alcoholic drinks
- be careful when driving a motor vehicle or operating machinery

If pregnant or breast-feeding, ask a health professional before use.

Keep out of reach of children. In case of overdose, get medical help or contact a Poison Control Center right away 1 (800) 222-1222

Directions

dosage should be taken one hour before travel starts

• adults and children 12 years of age and over: take 1 to 2 tablets once daily or as directed by a doctor

Other information

store at room temperature 20° – 25°C (68° –77°F)

Inactive ingredients

croscarmellose sodium, crospovidone, FD&C red #40 lake, lactose, magnesium stearate, raspberry flavor, silica, sodium saccharin, stearic acid, vanilla flavor.

Questions?

call toll-free 1 (844) 241-5454 or visit us on the web at www.bonine.com

ATTENTION: DO NOT USE IF CARTON IS OPEN OR IF BLISTER IS TORN OR MISSING.

Dist. by: **WellSpring Pharmaceutical Corporation** Sarasota, FL 34243 USA © WellSpring 2014

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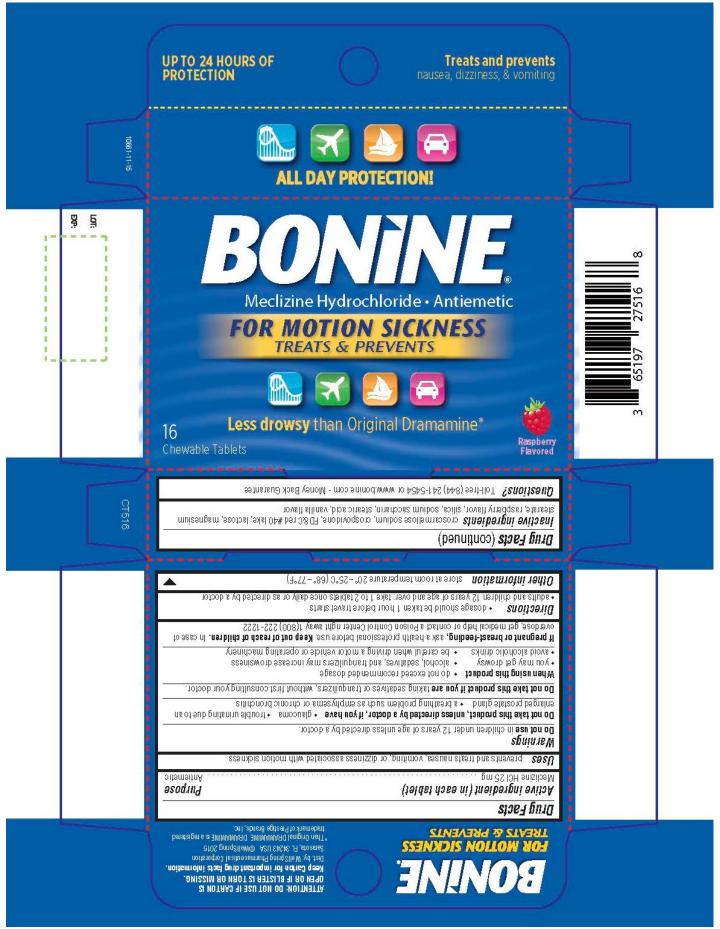
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PRINCIPAL DISPLAY PANEL 65197-275



Principal Display Panel 65197-296





Treats and prevents









ALL DAY PROTECTION!

Less drowsy than Original Dramamine*

Meclizine Hydrochloride • Antiemetic

FOR MOTION SICKNESS TREATS & PREVENTS











Chewable Tablets

Cuestions? Tollfree 1 (844) 241-5454 or www.boning.com - Money Back Guarantee

risepberry flavoř, silica gel, sodium saccharin

INACTIVE INGREDIENTS com starch, FD&C red #40 aluminum bler, taclose, magnesium stande,

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Drug Facts (continued)

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Do not take this product, unless directed by a doctor, if you have

Do not use in children under 15 years of age unless directed by a doctor.

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Active ingredient (in each tablet)

Drug Facts



TREATS & PREVENTS **LOR MOTION SICKNESS**



BONINE

meclizine hydrochloride tablet, chewable

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65197-275	
Route of Administration	ORAL			

l	Active Ingredient/Active Moiety				
l	Ingredient Name	Basis of Strength	Strength		
l	MECLIZINE HYDRO CHLO RIDE (UNII: HDP7W44CIO) (MECLIZINE - UNII:3L5TQ84570)	MECLIZINE HYDROCHLORIDE	25 mg		

Inactive Ingredients		
Ingredient Name	Strength	
CROSPOVIDONE (UNII: 2S7830E561)		
FD&C RED NO. 40 (UNII: WZB9127XOA)		
MAGNESIUM STEARATE (UNII: 70097M6I30)		
SILICON DIO XIDE (UNII: ETJ7Z6 XBU4)		
SACCHARIN SODIUM (UNII: SB8ZUX40TY)		
STEARIC ACID (UNII: 4ELV7Z65AP)		
CROSCARMELLOSE SODIUM (UNII: M28 OL1HH48)		
LACTOSE MONOHYDRATE (UNII: EWQ57Q8I5X)		
VANILLA (UNII: Q74T35078H)		
RASPBERRY (UNII: 4N14V5R27W)		

Product Characteristics						
Color	PINK (light pink)	Score	2 pieces			
Shape	ROUND	Size	9mm			
Flavor	RASPBERRY, VANILLA	Imprint Code	Bonine;201			
Contains	Contains					

P	Packaging				
#	Item Code	Package Description	Marketing Start Date	Marketing End Date	
1	NDC:65197-275-08	1 in 1 BOX	12/15/2014		
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product			
2	NDC:65197-275-16	2 in 1 BOX	12/15/2014		
2		8 in 1 BLISTER PACK; Type 0: Not a Combination Product			
3	NDC:65197-275-12	1 in 1 BOX	12/15/2014		
3		12 in 1 BOTTLE; Type 0: Not a Combination Product			
4	NDC:65197-275-02	2 in 1 POUCH; Type 0: Not a Combination Product	12/15/2014		

Marketing Inform	nation		
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date

BONINE

meclizine hydrochloride tablet, chewable

Product Information				
Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:65197-296	
Route of Administration	ORAL			

Active Ingredient/Active Moiety				
l	Ingredient Name	Basis of Strength	Strength	
ı	MECLIZINE HYDRO CHILO RIDE (UNII: HDP7W44CIO) (MECLIZINE - UNII:3L5TO84570)	MECLIZINE HYDROCHLORIDE	25 mg	

Inactive Ingredients				
Ingredient Name	Strength			
FD&C RED NO. 40 (UNII: WZB9127XOA)				
MAGNESIUM STEARATE (UNII: 70097M6I30)				
SACCHARIN SODIUM (UNII: SB8ZUX40TY)				
STARCH, CORN (UNII: O8232NY3SJ)				
SILICON DIO XIDE (UNII: ETJ7Z6XBU4)				
LACTO SE MONO HYDRATE (UNII: EWQ57Q8I5X)				
VANILLA (UNII: Q74T35078H)				
RASPBERRY (UNII: 4N14V5R27W)				

Product Characteristics					
Color	PINK	Score	2 pieces		
Shape	ROUND	Size	9mm		
Flavor	RASPBERRY	Imprint Code	Bonine;201		
Contains					

I	Packaging					
#	t Item Code	Package Description	Marketing Start Date	Marketing End Date		
1	NDC:65197-296-08	1 in 1 BOX	04/19/2017			
1		8 in 1 BLISTER PACK; Type 0: Not a Combination Product				
2	NDC:65197-296-16	2 in 1 BOX	04/19/2017			
2		8 in 1 BLISTER PACK; Type 0: Not a Combination Product				

Marketing Information			
Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
OTC MONOGRAPH FINAL	part336	04/18/2017	03/31/2019

Labeler - WellSpring Pharmaceutical Corporation (110999054)

Revised: 9/2020 WellSpring Pharmaceutical Corporation